



River Region Human Services

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August 9, 1999

Docket Management Branch
HFA 305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

RE: Proposal Rules. Docket # 98N-0617

The proposed rules change helps move opiate treatment into the mainstream of medical practice. The following is submitted for your consideration.

- 1) The "Transitional Certification" time period as proposed 8.11 (d) (page 39818) is too short from an administrative frame of reference to comply. There are 900 programs; (page 39811) that would require 10 programs daily to be transitionally certified.
- 2) Some programs (such as River Region) have OTP's that are currently accredited. Although the accreditation requirement will change, we should be grandfathered, or moved to the bottom of the list, with accreditation efforts focused on new accreditations.
- 3) We have a number of patients who have stable long-term recoveries. Their take home supply should be regulated the same as other prescription narcotics.
- 4) I support the regulatory reform, as it will provide for needed clinical flexibility, and will provide patients with a more "user friendly" program.

Sincerely,

Dick Warfel
Executive Director

98N-0617

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